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(54) Title: PACEMAKER EVALUATION METHOD AND APPARATUS

(57) Abstract: A method of optimizing the performance of a cardiac prosthetic pacing device including monitoring, optionally transcutaneously or non-invasively, the flow output from the heart; optionally using a continuous wave Doppler ultrasound device, followed by adjusting the timing of said cardiac prosthetic pacing device so as to optimize the flow from the heart under operational condition, optionally including different pharmacological conditions.

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PACEMAKER EVALUATION METHOD AND APPARATUS

FIELD OF THE INVENTION

The present invention relates to the field of cardiac pacemakers and, in particular, discloses a methodology and apparatus for selectively tuning a pacemaker-type device.

BACKGROUND OF THE INVENTION

Pacemaker devices normally consist of the pacemaker control unit containing a power cell such as a battery, a pacemaker lead and end electrodes which are attached to the heart so as to stimulate the heart into action at certain timed occurrences. Recent advances in pacemaker technology include providing for fully programmable capabilities. Modern pacemaker devices such as those available from Medtronic Inc often include on board processing and storage capabilities and the latest models allow for external communication with reader and control devices located outside the body for telecommunications. Examples of such systems are disclosed in US Patent Number 6,577,901 to Thompson, US Patent Number 6,580,946 to Struble and US Patent Application 2003/0100925 to Pape et al. the contents of each of which is incorporated by cross reference disclose suitable forms of heart pacemaker technology suitable for us with the present invention.

As is disclosed in the aforementioned patents, modern pacemaker devices also allow for a variability in operation of the heart in accordance with external needs. For example, during exercise, the pacemaker device may increase the heart rate. Further, during periods of rest, the pacemaker device may decrease the heart rate. Further, programmable pacemakers allow for storage of information for downloading as to the onboard operation of the pacemaker unit.

There is therefore a general need to accurately and succinctly tune the pacemaker unit for the proper operation of the heart muscle.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide for a method and apparatus for tuning the operation of pacemaker units to achieve more optimal results.

In accordance with a first aspect of the present invention, there is provided a method of tuning a cardiac prosthetic pacing device, the method comprising the steps of (a) monitoring the flow output from the heart; and (b) adjusting the timing of pacing events by

the cardiac prosthetic pacing device so as to optimise the flow from the heart under operational conditions.

Preferably, the method includes monitoring the flow utilising a continuous wave Doppler signal directed at the heart. Ideally, the method is repeated under a number of different operational conditions for a patient including walking and/or running. Further, preferably the method is repeated under a number of different pharmalogical conditions for a patient.

In accordance with a further aspect of the present invention, there is provided an apparatus for tuning a cardiac prosthetic pacing device, the apparatus including: monitoring means for non invasively monitoring the flow of blood out of the heart; control means for controlling the operation of the cardiac prosthetic pacing device including variation of the pacing rate; and processing means interconnected to the monitoring means and the control means, the processing means instructing the control means to vary the pacing rate of the cardiac prosthetic pacing device and monitor the corresponding measurement of the monitoring means.

Preferably, the monitoring means includes a continuous wave Doppler sensor device for emitting and receiving a CW- Doppler signal directed and reflected from the patient's heart.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 illustrates a first operational environment of the preferred embodiment;

Fig. 2 illustrates a sectional view through a transducer device;

Fig. 3 illustrates a velocity time snapshot as measured by the CW transducer device;

Fig. 4 illustrates various portions of the snapshot of Fig. 3;

Fig. 5 and Fig. 6 illustrates flowcharts of the steps involved in optimising the pacemaker arrangement of the preferred embodiment.

DESCRIPTION OF PREFERRED AND OTHER EMBODIMENTS

In the preferred embodiment, continuous wave ultrasound techniques are utilised to transcutaneously measure the cardiac output of a heart operating with a cardiac prosthetic pacing device. Through utilisation of ultrasound techniques, a measurement of cardiac

output can be obtained as a function of rate and volume. The ultrasound techniques also provide a measure of stroke volume thereby providing information for optimisation of settings of the pacemakers.

Turning initially to Fig. 1, there is illustrated one arrangement utilising the preferred embodiment. In this arrangement, a patient 10 has attached two non-invasive monitoring devices 11-13. Each of the two devices 11-13 are interconnected to a processing and display unit eg. 12, 14. Each of the units 12, 14 includes an internal computer processing means, a display and a series of control buttons for controlling the functionality of the device. Each of the devices 12, 14 are further networked to a base station or the like for overall monitoring and control.

The sensor 13 is in telemetry connection with the heart pacemaker unit. It is assumed that the device 14 in conjunction with sensor 13 is able to vary the rate at which the heart paces. Such systems are disclosed in the aforementioned patent applications.

Hence, variations in blood flow around the body can be measured by alteration of the heart pacemaker timing period whilst simultaneously monitoring the corresponding alteration in blood flows as detected by the CW transducer device. In this manner the pacing period can be optimised for the particular recipient by estimation of the flow requirements of the recipient given their size, weight etc.

Fig. 2 shows an example of the first actuator 11 for attachment to the skin surface. Ideally CW Doppler is utilised to monitor the blood flow within the heart. CW Doppler is a non-invasive technique in which ultrasonic signals from transducer elements are directed into a blood carrying vessel of a patient. Doppler shifts in the reflected signal provide an indication of the rate of blood flow. In Fig. 2, a transducer element 11 includes an ultrasonic transducer 15 attached to a positioning device 16 which can be used to initially set the position of the transducer. Between the transducer 15 and a patient's skin 17 is placed a gel coupling layer 18 for coupling the ultrasonic transducer vibrations to the skin 17. The principles of CW Doppler flow measurement are known. Patent Cooperation Treaty (PCT) publication number WO 99/66835 to the present assignee, the contents of which are incorporated herein by cross-reference, describes in more detail an ultrasonic transducer device suitable for measuring blood flow using the CW Doppler method.

In the embodiment shown in Fig. 1, the transducer elements are placed on the patient to obtain intra-cardiac or aortic signals, for example through a suprasternal notch.

The CW method detects the velocity of individual blood cells by measuring the frequency change of a reflected ultrasound beam and displaying this as a velocity time flow profile, an example of which is shown in Fig. 3. The transducer output forms an input to the processor unit which image processes the results of Fig. 3 so as to calculate from the velocity time flow profile, the velocity time integral (tvi) and other relevant information such as heart rate (HR) and peak volume Vpk. These calculations can then be compared with the pacemaker timing setting to determine an overall optimal performance.

The arrangement of Fig. 1 can then be translated into other real life situations. For example with the patient on a walking treadmill and a running treadmill. Again, measurements can be taken of variation in blood flow pumping rates with variation in heart rates so as to thereby tune the operation of the pacemaker unit for the particular individual to particular activities. These results can then be stored in the pacemaker unit for future use.

A flow chart of the overall steps involved in the operation of the preferred embodiment is illustrated generally 30 in Fig. 5. These include the steps of obtaining a CW Doppler flow measurement 31 and simultaneously obtaining pacemaker rate measurements 32. Next, a determination is made as to whether to increase or decrease the pacemaker rate measurement 33. Upon increasing or decreasing measurements, continual analysis of the change in flow rate is made 34.

Through the utilisation of flow measurements via the CW technique, advanced analysis can also be conducted in a more non invasive manner. Normally, pacemakers are designed to regulate cardiac output by controlling the timing of events in the cardiac cycle and are usually set according to ECG criteria. ECG devices however measure only the heart rate and make no measure of cardiac output, a function of rate and volume, which is a measure of how much the heart pumps. The CW method provides a measure of the heart rate and total volume the heart pumps thereby providing more information required for optimisation of the settings of pacemaker devices. Obviously, testing in accordance with a wide variety of physiologic (exercise) conditions or pharmacologic testing is desirable.

Modern pacing devices are conceived to optimise cardiac performance. Cardiac performance is a function of rate and output volume. Current methods for setting parameters are generally based on rate setting from an ECG. The ultrasound device 12 provides both rate and volume information so that pacemaker timing of cardiac events can be optimised. In particular, biventricular pacing devices allow asynchronous activation of ventricular

chambers. Indeed, the delay period between the activation of right and left ventricular chambers effect the optimal haemodynamic performance and varies with individual physiology and pathophysiology.

The use of the transcutaneous sensing of blood flow within the heart allows for the determination of optimal pacing delays in pacemaker devices leading to more appropriate use and effect of these devices.

Further, By carrying out a large number of tests on a large number of patients under a large number of different conditions, various indicies can be built up in guiding the system in setting the pacing rates for particular patient activities. The test can be carried out on a plurality of patients and the total set of results statistically combined, e.g. averaged for patient variables such as age, sex, weight etc.

Upon conducting an analysis of flow rate with activity type, a determination can be made of the desirable flow rate for standard activity types measurable with the type of pacemaker device utilised. The desirable flow rate for each activity type can then be uploaded to the pacemaker device and utilised to tune the pacemaker's operation. For example, Fig 6 illustrates a flow chart of one possible control loop within the pacemaker device. Utilising a precalculated stored table of correspondence between rate type and activity type 63, a given current activity type is input 63. The difference between a current rate and the activity type rate is calculated 61 and the current rate is slowly changed so that it is closer to the current activity rate. The system can operate in a feedback loop constantly with a predetermined delay 62.

Additionally, the invention as described herein can be used to improve understanding of the normal physiology and pathophysiology associated with cardiovascular function, exercise and pulmonary function.

It will be understood that the invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

The foregoing describes embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto, without departing from the scope of the present invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A method of tuning a cardiac prosthetic pacing device, the method comprising the steps of:

(a) monitoring the flow output from the heart;

(b) adjusting the timing of pacing events by said cardiac prosthetic pacing device so as to optimise the flow from the heart under operational conditions.

2. A method as claimed in claim 1 wherein said step (a) further comprises the step of monitoring the flow utilising a transcutaneous continuous wave Doppler signal directed at the heart.

3. A method as claimed in claim 1 wherein said method is repeated under a number of different operational conditions for a patient including walking and/or running.

4. A method as claimed in claim 1 wherein said method is repeated under a number of different pharmalogical conditions for a patient.

5. An apparatus for tuning a cardiac prosthetic pacing device, the apparatus including:

monitoring means for non invasively monitoring the flow of blood out of the heart;

control means for controlling the operation of the cardiac prosthetic pacing device including variation of the pacing rate;

processing means interconnected to said monitoring means and said control means, said processing means instructing said control means to vary the pacing rate of said cardiac prosthetic pacing device and monitor the corresponding measurement of said monitoring means.

6. An apparatus as claimed in claim 5 wherein said monitoring means includes a continuous wave Doppler sensor device for emitting and receiving a CW- Doppler signal at a patients heart.

7. A method for tuning a cardiac prosthetic pacing device substantially as hereinbefore described with reference to the accompanying drawings.

8. An apparatus for tuning a cardiac prosthetic pacing device substantially as hereinbefore described with reference to the accompanying drawings.

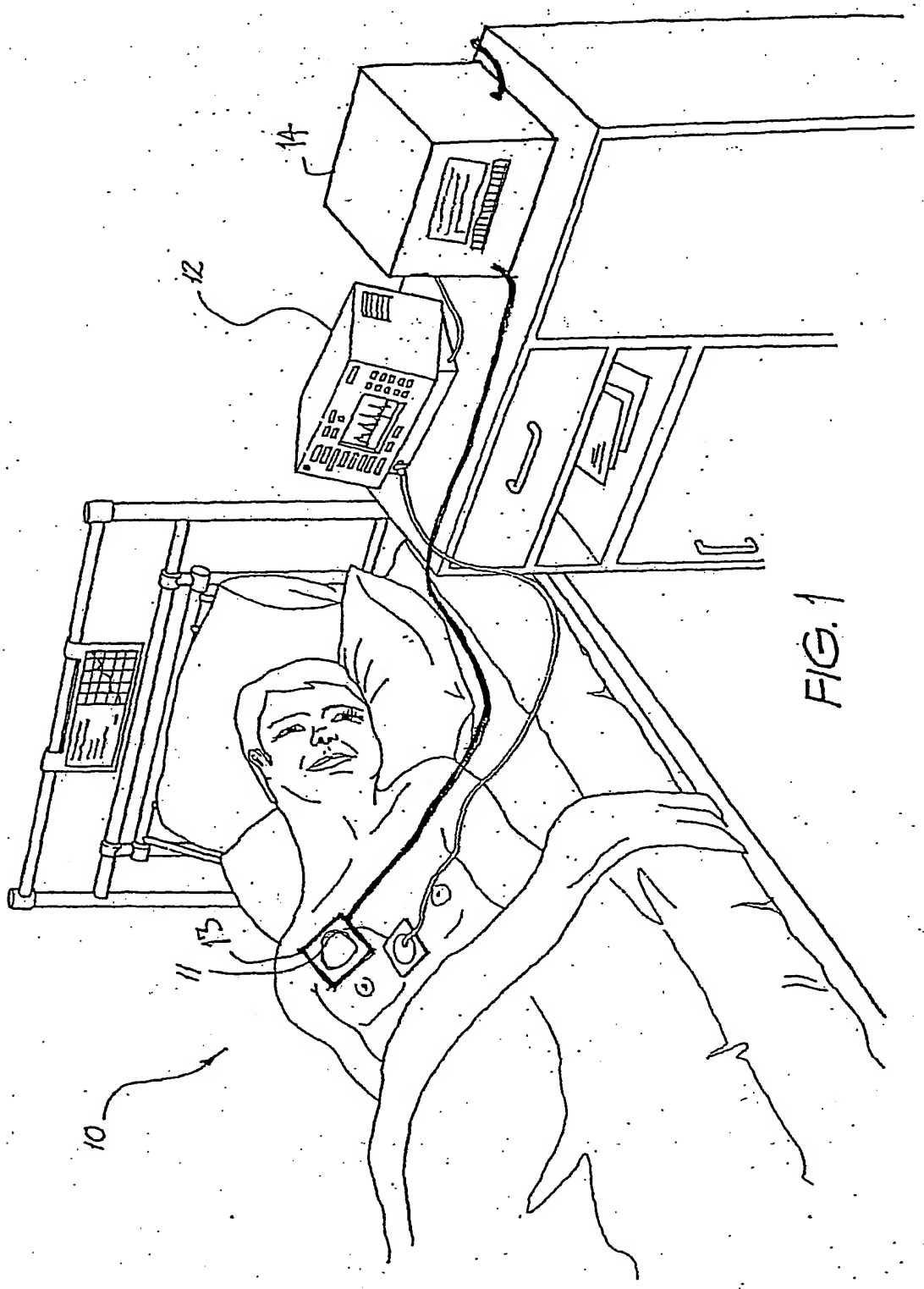


FIG. 1

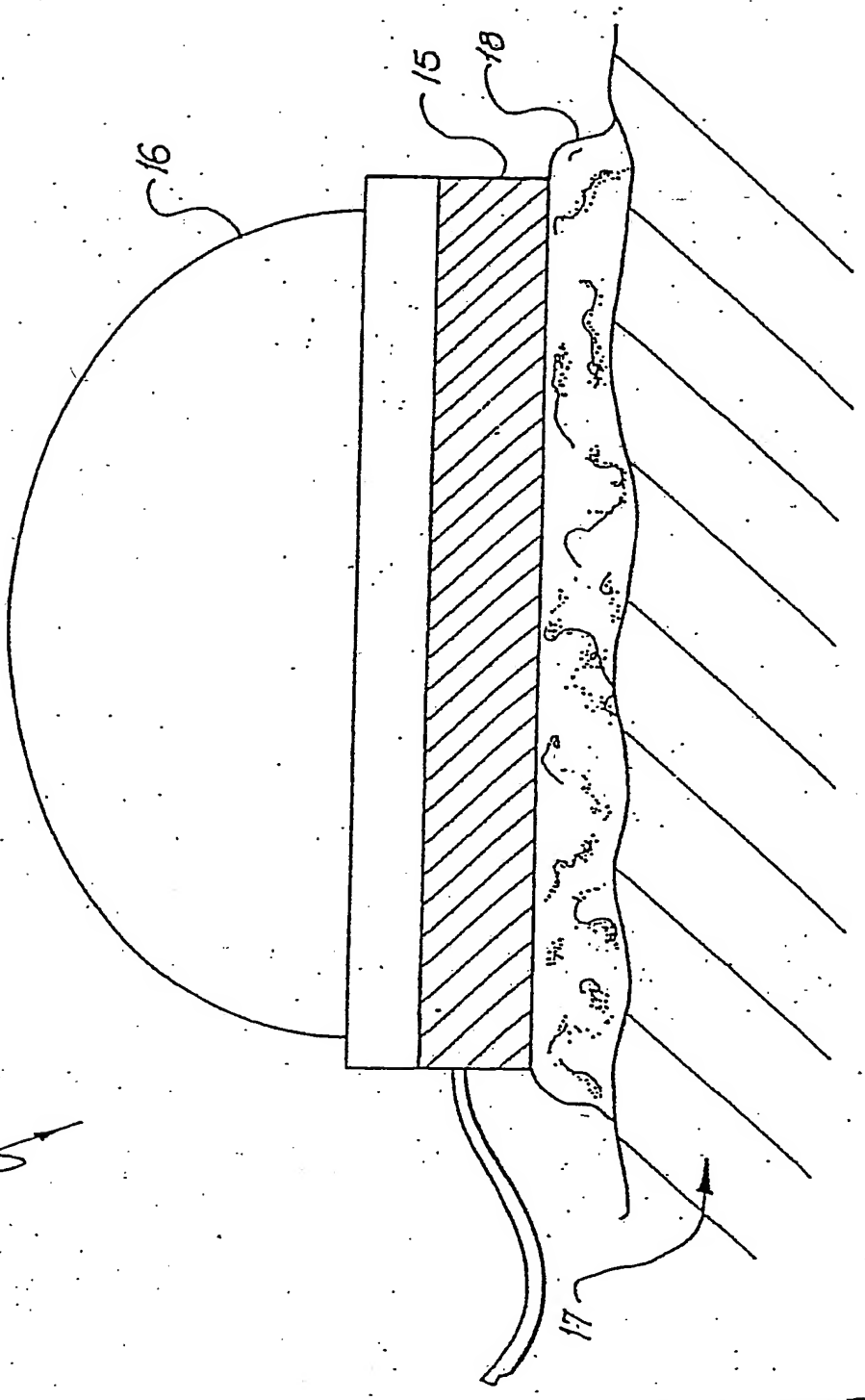
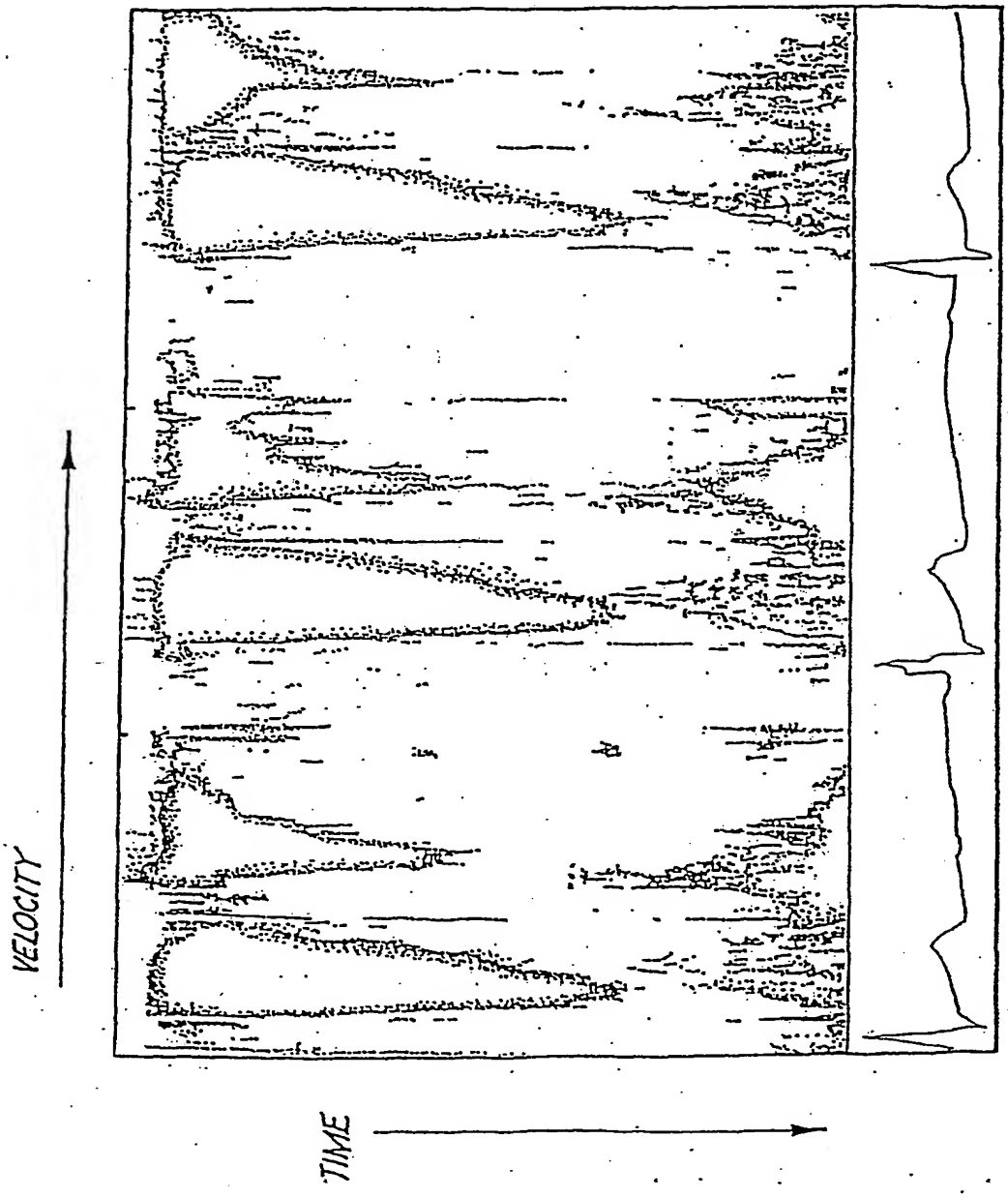


FIG. 2

Fig. 3



Inventor: [redacted]
Docket No. [redacted]0.0008USWO
Title: PACEMAKER EVALUATION METHOD AND APPARATUS
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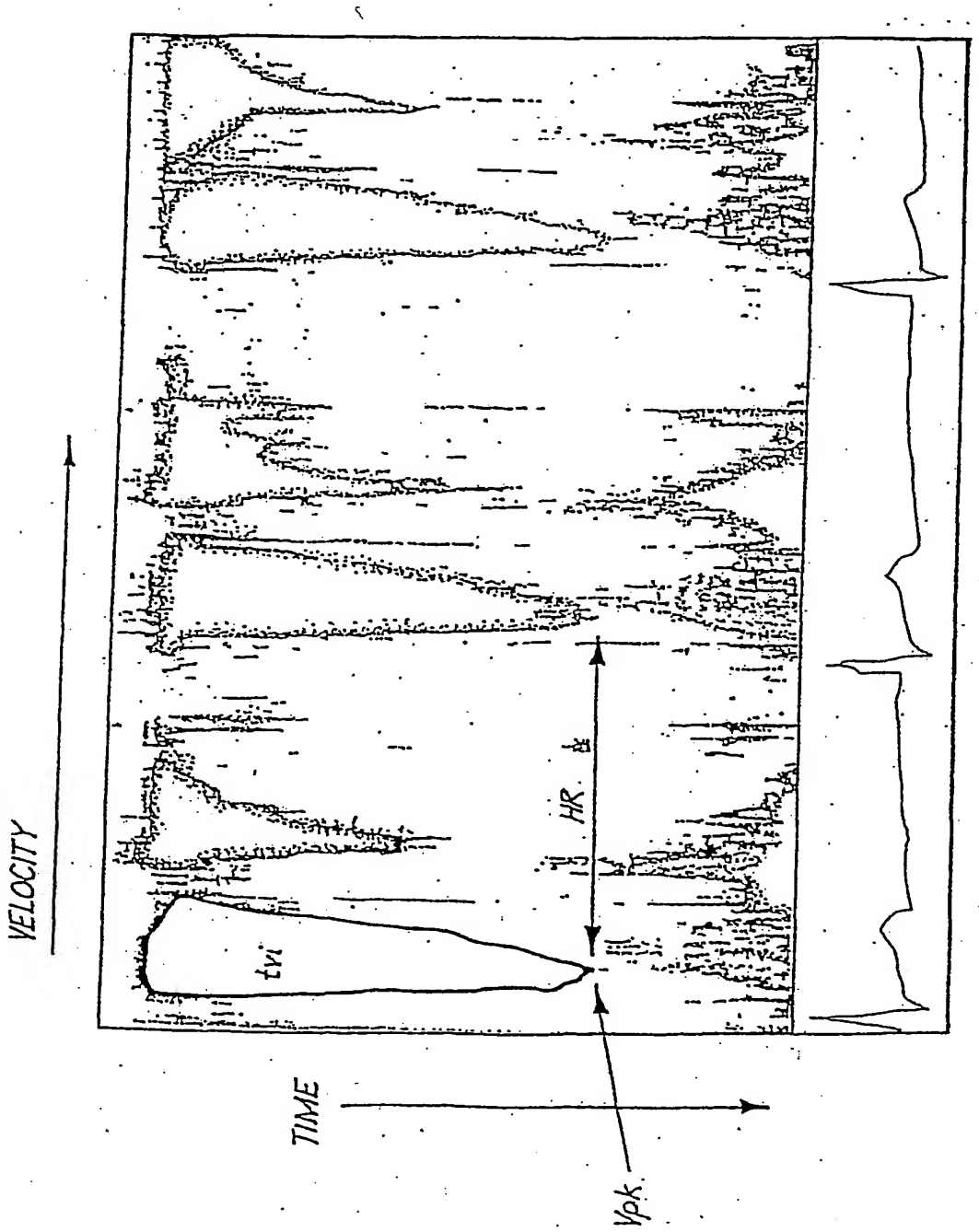
Sheet 4 of 6

Fig. 4



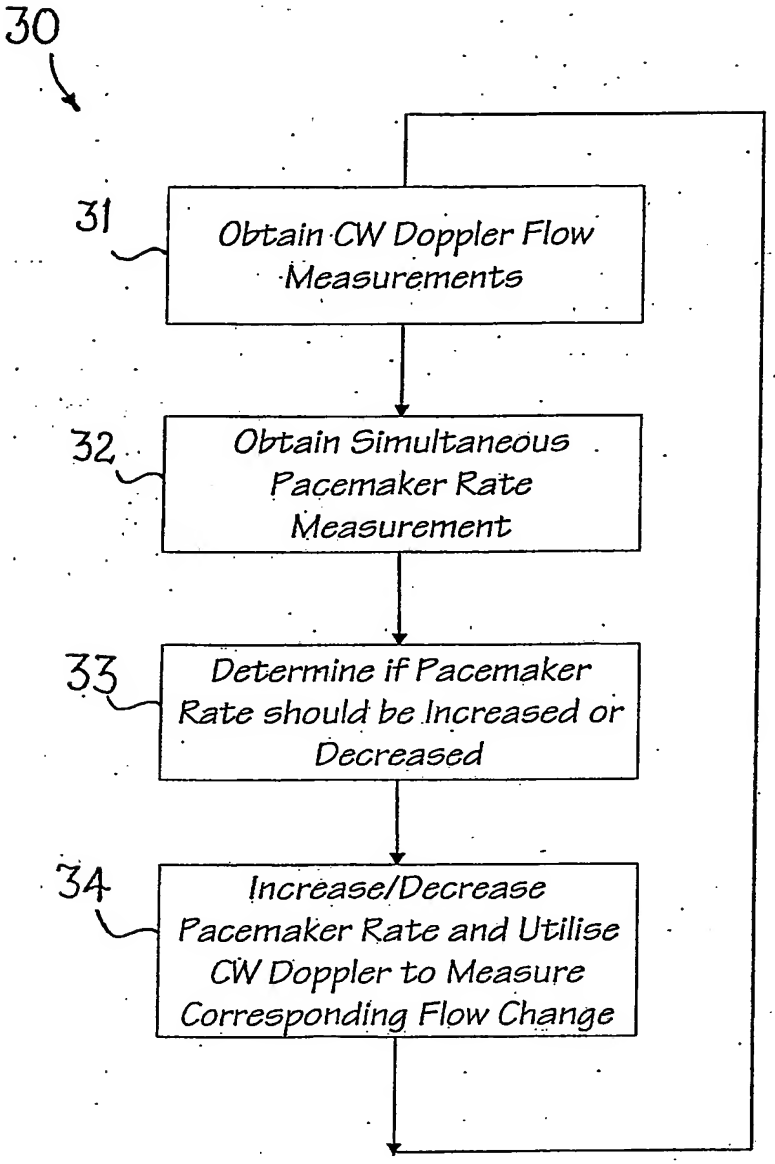

30
31
Obtain CW Doppler Flow Measurements
32
Obtain Simultaneous Pacemaker Rate Measurement
33
Determine if Pacemaker Rate should be Increased or Decreased
34
Increase/Decrease Pacemaker Rate and Utilise CW Doppler to Measure Corresponding Flow Change

Fig. 5

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Docket [redacted]50.0008USWO
Title: PA[redacted]AKER EVALUATION METHOD AND APPARATUS
Attorney Name: Brian H. Batzli
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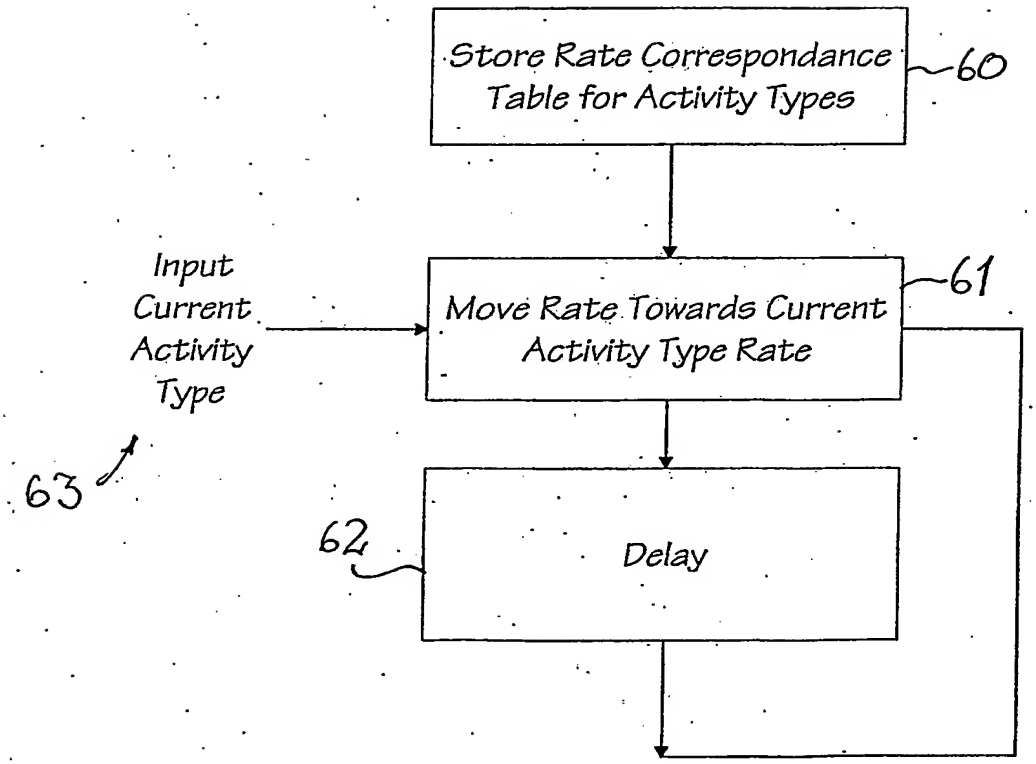

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/00807

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61N 1/365, A61B 8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: A61B 5/-, A61M 1/-, A61N 1/- and keywords; heart, cardiac, pacing, rhythem, flow, volume, output, deliver, continuous wave, Doppler, ultrasound, tune, optimum, calibrate, adjust, feedback, regulate, transcutaneous & similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 474957 A2 (FEREK-PETRIC et. al.) 18 March 1992 See col 9, lines 45 to 52	1, 3
X	EP 503285 A1 (TELECTRONICS N.V.) 16 September 1992 See col 1, lines 1 to 12; col 2, line 35	1, 3
X	US 5139020 A (KOESTNER et. al.) 18 August 1992 See col 6, line 63 to col 7, line 14; col 21	1, 3

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 July 2003	- 5 AUG 2003
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer VINCE BAGUSAUSKAS Telephone No : (02) 6283 2110

INTERNAT[redacted]L SEARCH REPORT

[redacted]nternational application No.
PCT/AU03/00807

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6285898 B1 (BEN-HAIM) 4 September 2001 See col 10, lines 60 to 67; col 23 lines 15 to 38; col 31, lines 1 to 48	1, 3, 5, 7, 8
X	US 5183040 A (NAPPHOLZ et. al.) 2 February 1993 See the Abstract; Fig 11, item 170; col 16, line 29; col 18, lines 50 to 54	1, 3, 4
X	WO 95/19806 A1 (PACESETTER AB) 27 July 1995 See page 6, lines 1 to 12; page 12, lines 27 to 30	1, 3
X	WO 00/62858 A2 (CARDIAC PACEMAKERS INC.) 26 October 2000 See page 13, lines 13 to 18	1, 3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU03/00807

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member					
EP 474957	DE	69122015	US	5318595		
EP 503285	US	5156157				
US 5139020	NONE					
US 6285898	CA	2144946	JP	8504653		
US 5183040	NONE					
WO 95/19806	HR	940035	JP	9508029		
WO 00/62858	AU	692789	EP	679068	US	6066094

END OF ANNEX